

## REMARKS

### **A. Introduction**

Applicants have carefully reviewed the Office Action mailed May 7, 2007. By this Amendment, claims 83-90 are added, claims 1, 4, 9, 40, 48, 50 are amended, and claims 5, 7-8, 10-27, 29-30, 32-39, 42-47, 52, 54-67, 69, 71, 73-75, and 78-82 are cancelled. Claims 28, 31, 53, and 68 were previously cancelled. Applicants have made these amendments to focus the present application and to advance prosecution in order to obtain allowance at the earliest possible date. Accordingly, no admission may be inferred from these amendments. Applicants expressly reserve the right to pursue the originally filed claims in the future. Additionally, Applicants submit that the amendments made herein introduce no new matter.

### **B. Independent Claim 1 (and Its Dependent Claims) Are Patentable Over U.S. Patent No. 3,292,613 to MacLeod ("MacLeod")**

Applicants respectfully submit amended independent claim 1 is novel and nonobvious over MacLeod. MacLeod fails to disclose negative pressure pulses of specific duration as recited in claim 1. The relevant limitation is as follows:

“wherein an element is provided to generate pulses of negative pressure within the chamber that can be transmitted to the limb directly via the liquid, the element being adapted to generate negative pressure for *between 5 and 15 seconds* and to release negative pressure for *between 5 and 10 seconds*”

As can be seen, claim 1 recites pressure generation for between 5 and 15 seconds and pressure release for between 5 and 10 seconds. Thus, the shortest claimed negative pressure pulse is 10 seconds (5 seconds generation and 5 seconds release).

Examiner has conceded that such pressure pulses are not anticipated by MacLeod. MacLeod teaches only synchronizing pressure pulses to the heartbeat. Certainly, such pulses are much shorter than those recited in claim 1.

Moreover, Applicants further submit that the evidence of record refutes any assertion that the claimed pressure pulses would have been obvious in light of

MacLeod's pressure pulses. The specification of the present application describes several advantages over systems like that of MacLeod, which produce pressure pulses synchronized to a patient's heartbeat. For example, page 21 (lines 15-17) states,

"In a number of earlier known systems in which an oscillating pressure was applied to a patient, it was thought best to vary pressure in time with the heart beat. The present inventors have found that a longer period to the oscillation is better."

Additionally, the following portions of the specification describe how longer pressure pulses produce remarkable increases in blood velocity without constricting the diameter of the blood vessels:

- "[I]t has been found that a preferred embodiment can improve blood velocity by up to at least 30% in the brachial artery." (Page 15, lines 9-10.)
- "In experiments, an average of at least 50% increase in blood velocity and an increase of 200% in a single subject have been witnessed. By pulsating the pressure, it is believed to facilitate the immediate and repeated increase of blood velocity without inducing a reflex constriction as a result of the venus pooling." (Page 15, lines 10-14.)
- "Figure 4 shows a detailed one minute recording. The negative pressure is built up for 10 seconds and released for 7 seconds (upper panel). The blood velocity in the brachial artery is measured outside the pressure chamber 4. The blood velocity increases to a certain point, about -25 mmHg (-3.4 kPa), before it drops. This is thought to be due to a reflex constriction of the arteries because of the venus pooling. Letting the pressure drop again, facilitates the immediate and repeated increase of blood velocity without the reflex restricting the blood flow as can happen with a constant negative pressure." (Page 31, line 21 through page 32, line 2.)

The test trial discussed on pages 36-38 of the specification cites even more advantages provided by embodiments of the present invention.

Furthermore, perhaps the most important piece of evidence is the Rule 1.132 Affidavit of Erling Bekkestad Rein, submitted on February 15, 2007. In his Affidavit, Mr. Rein details an experiment he conducted to test the efficacy of applying the claimed negative pressure pulses. (Affidavit at 3-11.) Based on this experiment, Mr. Rein concludes, "The results show that applying pulses of negative pressure at the claimed

intervals has a remarkable impact on blood velocity, while doing so at other intervals does not.” (*Id.* at 3.)

Applicants also respectfully submit that secondary considerations (see MPEP 2141(III)) likewise support Applicants’ position that the claimed pressure pulses are nonobvious. Mr. Rein’s Affidavit notes that he and his co-inventor were able to publish an article titled “Hypothermia During Laparotomy Can Be Prevented by Locally Applied Warm Water and Pulsating Negative Pressure” in the prestigious British Journal of Anaesthesia. This shows that those skilled in the art have taken notice of at least certain aspects of the present invention. Moreover, Mr. Rein’s Affidavit also notes that sales of a commercial embodiment of the present invention have earned \$500,000—a tribute to the present invention’s commercial success. Indeed, Applicants submit that neither the peer recognition nor the commercial success would have resulted if the present invention was nothing more than an obvious extension of MacLeod’s 45-year-old technology. Accordingly, Applicants respectfully submit that independent claim 1 and its dependent claims (2-4, 6, 9, 70, 72, 76-77, 83-84) are patentable over MacLeod.

***C. Independent Claims 48 and 50 (and Their Dependent Claims) Are Patentable Over MacLeod in View of U.S. Patent No. 5,683,438 to Grahn (“Grahn”) and U.S. Patent No. 3,878,839 to Norton et al. (“Norton”)***

Applicants respectfully submit that independent claims 48 and 50 are patentable for at least the reasons set forth above in connection with claim 1. Claims 48 and 50 likewise recite specific negative pressure pulses. The relevant limitations are as follows:

- claim 48 – “generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for *between 5 and 15 seconds* and released for an interval of *between 5 and 10 seconds* the pulses of negative pressure and thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid”
- claim 50 – “generating pulses of negative pressure within the chamber of between -20 mmHg and -80 mmHg (-2.7 kPa and -10.7 kPa), each pulse of negative pressure being generated for *between 5 and 15 seconds* and released for an interval of *between 5 and 10 seconds* the pulses of negative pressure and

thermal energy in the liquid being transmitted simultaneously to the limb of the patient via the direct contact with the liquid”

Again, Examiner has conceded that MacLeod does not teach such pressure pulses. Also, as set forth above, the claimed pressure pulses are not obvious in light of MacLeod’s pulses. Moreover, neither Grahn nor Norton can remedy MacLeod’s deficiencies. Accordingly, Applicants respectfully submit that independent claims 48 and 50, and their dependent claims (41, 49, 85, 87-88 and 40, 51, 86, 89-90, respectively), are patentable over MacLeod in view of Grahn and Norton.

***D. Dependent Claims 49, 51, 70, 72, 76, and 87-90 Are Patentable Over the Cited Art***

Applicants respectfully submit that dependent claims 49, 51, 70, 72, 76, and 87-90 distinguish over the cited art to an even greater degree than their corresponding independent claims. These claims recite even more specific pressure pulses. Claims 70, 72, and 76, which depend from claim 1, include the following limitations:

- claim 70 – “wherein the element is adapted to release negative pressure for 7 seconds”
- claim 72 – “wherein the element is adapted to generate negative pressure for 10 seconds”
- claim 76 – “wherein the element is adapted to generate negative pressure for 10 seconds and to release negative pressure for 7 seconds”

Claims 49, 87, and 88, which depend from claim 48, include the following limitations:

- claim 49 – “wherein the negative pressure is generated for 10 seconds and then released for 7 seconds”
- claim 87 – “wherein each pulse of negative pressure is generated for about 10 seconds”
- claim 88 – “wherein each pulse of negative pressure is released for about 7 seconds”

Claims 51, 89, and 90, which depend from claim 50, include the following limitations:

- claim 51 – “wherein the negative pressure is generated for 10 seconds and then released for 7 seconds”
- claim 89 “wherein each pulse of negative pressure is generated

for about 10 seconds”

- claim 90 – “wherein each pulse of negative pressure is released for about 7 seconds”

MacLeod clearly does not teach any of the pressure pulses recited in these claims. Once again, the claimed pressure pulses are not obvious in light of MacLeod’s pulses, nor can Grahn, Norton, or any of the other cited art remedy MacLeod’s deficiencies.

Accordingly, Applicants respectfully request that Examiner allow dependent claims 49, 51, 70, 72, 76, and 87-90.

### ***E. Conclusion***

In view of the foregoing, Applicants respectfully submit that this application stands in condition for allowance. Applicants respectfully request favorable consideration and prompt allowance. The Commissioner is hereby authorized to charge any additional filing fees required and/or to credit any overpayment to Deposit Account No. 06-1910. Examiner is invited to telephone the undersigned if believed to be useful to advance prosecution.

Respectfully submitted,

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/Thomas R. Hipkins/  
Thomas R. Hipkins, Reg. No. 57,659  
(612) 492-7307

Customer No.: 022859  
Fredrikson & Byron, P.A.  
200 South Sixth Street, Suite 4000  
Minneapolis, MN 55402-1425 USA  
Facsimile: (612) 492-7077

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